K121132

MAY 10 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date

March 30, 2012

Manufacturer

HUMANRAY Co., Ltd.
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Contact person: Mr. Dave Kim

Trade/Proprietary Name: EzSensor P

Common Name:

Medical Image Processing Unit

Classification Name:

Solid State X-Ray Imager (21CFR 892.1650, Product Code MQB)

Description:

The EzSensor P digital intra oral sensor is a solid state x-ray imager designed for dental radiographic applications. The EzSensor P digital intra oral sensor provides digital diagnostic image capture to replace radiographic film/screen systems in general dental diagnostic procedures. The captured digital image is

transferred to personal computer via USB interface port.

Indication for use:

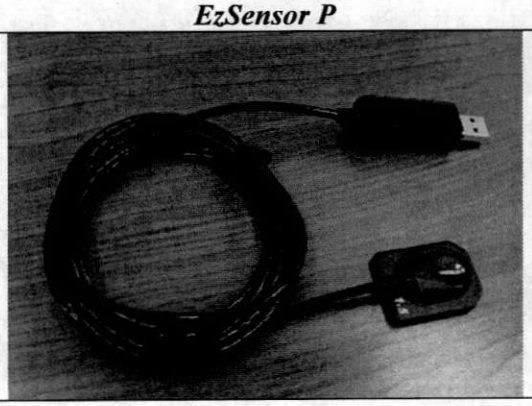
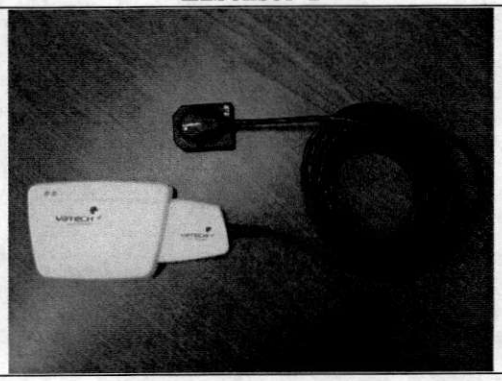
EzSensor P, Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

Predicate Device:

Manufacturer	: HUMANRAY Co., Ltd.
Device	: EzSensor T
510(k) Number	: K113360 (Decision Date – February 7th, 2012)

Substantial Equivalence:

The EzSensor P digital intra oral sensor described in this 510(k) has the same intended use and similar technical characteristics as EzSensor T of HUMANRAY Co., Ltd.

Characteristic	**Proposed** **HUMANRAY Co., Ltd.** ***EzSensor P***	**Predicate** **HUMANRAY Co., Ltd.** **EzSensor T**
Feature		
510(k) number	-	K113360
Indications for use	EzSensor P, Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.	EzSensor T, Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.
Device Description	EzSensor P is a solid state x-ray imager designed for dental radiographic	EzSensor T is a solid state x-ray imager designed for dental radiographic

	applications. The EzSensor P digital intra oral sensor provides digital image capture to replace radiographic film/screen systems in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port.	applications. The EzSensor T digital intra oral sensor provides digital image capture to replace radiographic film/screen systems in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port.
Sensor Dimension(mm)	Size "1.5" : 38.7 x 29.2 Size "2.0" : 42.8 x 31.5	Size "1.0" : 36.8x26.1 Size "1.5" : 38.7x29.2 Size "2.0" : 42.8x31.5
Sensor Thickness	4.95	4.95
Active Area(mm)	Size "1.5" : 24.01 x 33.04 Size "2.0" : 26.04 x 36.05	Size "1.0" : 20.02x30.03 Size "1.5" : 24.01x33.04 Size "2.0" : 26.04x36.05
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module
Pixel Size(㎛)	20x20	35x35
Pixel Matrix	Size "1.5" : 1200x1650 pixel Size "2.0" : 1300x1800 pixel	Size "1.0" : 572x858 pixel Size "1.5" : 686x944 pixel Size "2.0" : 744x1030 pixel
Pixel Pitch(Spacing)	0.02 ㎜ x 0.02 ㎜	0.035 ㎜ x 0.035 ㎜
Theoretical Resolution	25 lp/㎜	14.1 lp/㎜

The indications for use, material, form factor, performance, and safety characteristics between EzSensor P and its predicate device are the same. The primary difference is Pixel size, Pixel matrix, Pixel pitch, Resolution and Scintillator materials; Cesium iodide(CsI) for EzSensor P and GOS(Gd2O2S:Tb) for EzSensor T, respectively. Accordingly we can claim the substantially equivalence of EzSensor P to the predicate device.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 (A1+A2, 1995), IEC 60601-1-1(2nd edition, 2000) for use with IEC60601-1(A1+A2, 1995) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the

Submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. HUMANRAY Co., Ltd. concludes that EzSensor P is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Humanray Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberly Lane
HOUSTON TX 77079

MAY 10 2012

Re: K121132
Trade/Device Name: EzSensor P
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 13, 2012
Received: April 13, 2012

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known):

Device Name: EzSensor P

Classification: Solid State X-Ray Imager

Indications for Use:

EzSensor P, Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

Prescription Use____√___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121132